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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-------------------------|-------------|----------------------|---------------------|------------------|
| 09/653,563 | 08/31/2000 | Martin Winn | 5594.US.P9 | 4178 |
| 23492 | 7590 | 07/29/2005 | EXAMINER | |
| | | | SHIAO, REI TSANG | |
| | | ART UNIT | | PAPER NUMBER |
| | | 1626 | | |
| DATE MAILED: 07/29/2005 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/653,563 | WINN ET AL. |
| | Examiner | Art Unit |
| | Robert Shiao | 1626 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on responses filed on 06/03, 2005.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1,21 and 157-191 is/are pending in the application.
4a) Of the above claim(s) 1,21,157-169,172-174,177-184 and 187-189 is/are withdrawn from consideration.

5) Claim(s) 170,175,185 and 190 is/are allowed.

6) Claim(s) 171,176,186 and 191 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 2/22/2001.
4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
5) Notice of Informal Patent Application (PTO-152)
6) Other: ____.

DETAILED ACTION

1. Claims 1, 21, and 157-191 are pending in the application.

Responses to Election/Restriction

2. Applicant's election without traverse of Group V claims 170-171, 175-176, 185-186, 190-191 in the reply filed on June 03, 2005, is acknowledged.

Status of the Claims

3. Claims 1, 21, and 157-191 are pending in the application. The scope of the invention of the elected subject matter is as follows:

Claims 170-171, 175-176, 185-186, 190-191, are drawn to methods of use (i.e., treating pain). Claims 1, 21, 157-169, 172-174, 177-184, and 187-189 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

The requirement is still deemed proper and is therefore made **FINAL**.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 171, 176, 186, and 191 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains

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subject matter "treating pain associated with bone cancer", which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention, i.e., see claim 171, line 1, and pages 1-2 and 15 of the specification.

5. Claims 171, 176, 186, and 191 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the instant compounds treating nociception, does not reasonably provide enablement for instant compounds treating pain associated with bone cancer. The specification does not enable any person skilled in the art to which it pertains, with which it is most nearly connected, to use the invention commensurate in scope with these claims, i.e., see claim 171, line 1.

For rejections under 35 U.S.C. 112, first paragraph, the following factors must be considered (*In re Wands*, 8 USPQ2d 1400, 1988):

- 1) Nature of invention.
- 2) State of prior art.
- 3) Level of ordinary skill in the art.
- 4) Level of predictability in the art.
- 5) Amount of direction and guidance provided by the inventor.
- 6) Existence of working examples.
- 7) Breadth of claims.
- 8) Quantity of experimentation needed to make or use the invention based on the content of the Disclosure.

See below:

1) Nature of the invention

The claims are drawn to a method of use using instant claimed compounds treating pain associated with bone cancer.

2) State of the prior art

The reference Patt et al. US 6,017,951 does not indicate which compounds of instant compounds may be useful in the claimed invention. Patt et al. '951 is pertaining to butenolide endothelin antagonists.

3) Level of ordinary skill in the art.

The level of ordinary skill in the art is high. The claims are drawn to a method of use using instant claimed compounds treating pain associated with bone cancer, by the instant examples disclosed in the specification.

4) Level of predictability in the art.

The claims are drawn to a method of use using instant claimed compounds treating pain associated with bone cancer, there would be little predictability in the scope of claimed methods.

5) Amount of direction and guidance provided by the inventor.

The claims are a method of use using instant claimed compounds treating pain associated with bone cancer, which are neither enabled nor supported in the specification.

6) Existence of working examples.

The claims are drawn to a method of use using instant claimed compounds

treating pain associated with bone cancer, however, the specification provides only limited examples of methods.

7) Breadth of claims.

The claims are extremely broad due to the vast number of possible "a method of use using instant claimed compounds treating pain associated with bone cancer".

8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The specification did not enable any person skilled in the art to which it pertains to make or use the invention commensurate in scope with this claim. In particular, the specification failed to enable the skilled artisan to practice the invention without undue experimentation. The skilled artisan would have a numerous methods in order to obtain "a method of use using instant claimed compounds treating pain associated with bone cancer" as claimed. Based on the unpredictable nature of the invention and state of the prior art and the extreme breadth of the claims, one skilled in the art could not perform the claimed compounds without undue experimentation, see *In re Armbruster* 185 USPQ 152 CCPA 1975.

6. Claims 170, 175, 185 and 190 are neither anticipated nor rendered obvious over the art of record, and therefore are allowable. This invention relates to endothelin antagonists.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Shiao whose telephone number is (571) 272-0707. The examiner can normally be reached on 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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July 26, 2005